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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,763	10/06/2003	Barry M. Yomtov	17509-0072	8563

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EXAMINER	
SMITH, TERRI L	
ART UNIT	PAPER NUMBER
3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/679,763	YOMTOV ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 20-36* is/are pending in the application.

4a) Of the above claim(s) *4,8-11,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,12-17,20-28 and 31-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5-30-06; 10-3-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 30 May 2006 have been fully considered but they are not persuasive. Examiner respectfully disagrees with Applicant's argument on page 15 lines 1–5 of the **Remarks** that "The structures and methods of Thompson therefore are entirely distinct from those for electrothermal ablation. Thompson clearly fails to disclose or remotely suggest a structure or means for electrothermal ablation and therefore clearly fails to teach Applicants' claimed devices and methods."

2. Applicant's amended claim 1 includes the following means-plus-function language: "means for disintegrating one or more of the reservoir caps by electrothermal ablation to release the at least one drug from one or more of the reservoirs." Applicant's specification discloses means for disintegrating on page 3 line 24–page 4 line 1 as "a means for actively disintegrating the reservoir cap. For example, the reservoir cap can comprise an electrically conductive material and the means for actively disintegrating the reservoir cap can comprise an input lead and an output lead each connected to the reservoir cap and a power source for delivering an effective amount of electrical current through the reservoir cap, via the input lead and output lead, to heat and rupture the reservoir cap to release the drug." Applicant's specification further discloses electrothermal ablation on page 14 lines 24–39 as "The reservoir cap is operably (i.e. electrically) connected to an electrical input lead and to an electrical output lead, to facilitate flow of an electrical current through the reservoir cap. When an effective amount of an electrical current is applied through the leads and reservoir cap, the temperature of the reservoir cap is locally increased due to resistive heating, and the heat generated within the reservoir cap

increases the temperature sufficiently to cause the reservoir cap to be electrothermally ablated (i.e., ruptured)."

3. 35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and **equivalents thereof**." (emphasis added by Examiner) Thompson, U.S. Patent Application 2002/0111601 clearly teaches the amended limitation set forth in claim 1 as stated herein above where the reservoir cap (e.g. Fig. 6, element 270) can comprise an electrically conductive material (paragraph [0066] lines 8–10) and the means for actively disintegrating the reservoir cap can comprise an input lead (e.g. 280, conductor lead) and an output lead (e.g. 286, conductor) each connected to the reservoir cap (e.g. as shown in Fig. 6 at the designated elements) and a power source for delivering an effective amount of electrical current through the reservoir cap (e.g. Fig. 1, element 2, IMD contains a power source), via the input lead and output lead, to heat and rupture the reservoir cap to release the drug (e.g. paragraphs [0071]–[0072] teaches an equivalent thereof to rupture (i.e.; dissolve) the reservoir cap to release the drug).

4. Additionally, in further support of the electrothermal technique, in paragraph [0005], Thompson teaches an electro-release system in combination with electrical stimulation.

5. Examiner further respectfully disagrees with Applicant's argument on page 15 lines 13 – 17 in the **Remarks** for the same reasons stated herein above. Consequently, Examiner will once again use the said Thompson prior art in this Office Action because it anticipates the claimed invention as set forth in the application. Examiner will also once again use the prior art of Santini, Jr. et al., U.S. Patent 5,797,898, Mann et al., U.S. Patent Application Publication

2002/0055761 and Barrett et al. U.S. Patent 6,587,719 as obvious over Thompson in this Office Action for the same reasons stated herein above.

6. Examiner thanks Applicant for noting and correcting the error in paragraph 2 of the Office Action mailed on 21 February 2006 where the elected Subspecies should have been B rather than A.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1–3, 5–7, 12–16, 20–28, 31–32, 35 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by Thompson, Patent Application Publication U.S. 2002/0111601.

9. Regarding claims 1 and 23, Thompson discloses an implantable drug delivery module (e.g. Fig. 1–3) which comprises a plurality of reservoirs (e.g. Fig. 6, elements 260 and 262), a release system contained in each of the reservoirs (e.g. Figs. 5–6; paragraph [0071]), wherein a release system comprises at least one drug (e.g. Fig. 6, elements 264 and 266), a plurality of discrete reservoir caps separating a release system from an environment outside of the reservoirs (e.g. Fig. 6, elements 270 and 272), and means for disintegrating one or more of the reservoir caps by electrothermal ablation to release the at least one drug from one or more of the reservoirs (e.g. Fig. 6; paragraph [0066] lines 8–10; paragraphs [0068]–[0072]); a neural electrical stimulator (e.g. Figs. 1–2) which comprises a signal generator (e.g. element 2, IMD) and at least one stimulation electrode for operable engagement with a neural tissue of a patient wherein at

least one stimulation electrode is connected to a signal generator (e.g. Fig. 1; paragraph [0037] lines 8–12); and at least one microcontroller for controlling operational interaction of a drug delivery module and a neural electrical stimulator (e.g. Fig. 5; paragraph [0011], lines 2–5; paragraph [0037], lines 10–13).

10. Further regarding claim 23, for the phrase "implanting into the patient the implantable drug delivery module of the medical device of claim 1," it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). Nonetheless, Thompson discloses implanting into a patient an implantable drug delivery module (e.g. Fig. 3, element 2).

11. With respect to claims 2, 3 and 5–7, Thompson discloses at least one microcontroller controls both a signal generator and a means for disintegrating one or more of the reservoir caps of a drug delivery module (e.g. Fig. 5; paragraphs [0071]–[0072]) (claim 2); a power source operably connected to a neural electrical stimulator (e.g. paragraph [0037]) (claim 3); a hermetically sealed encasement containing a drug delivery module and microcontroller wherein a stimulation electrode extends a distance from a hermetically sealed encasement (claim 5) and a flexible catheter connects a stimulation electrode to an encasement (claim 6) (e.g. Figs. 1–2; paragraph [0037], lines 8–11); telemetry components in operable communication with a microcontroller (claim 7) (e.g. Fig. 5; paragraph [0052], lines 8–10).

12. For claims 12–15, 31 and 35, Thompson discloses adapted to treat chronic pain (claims 12 and 31) (e.g. paragraph [0049], lines 12–14; paragraph [0064], line 21), a movement disorder (claims 13 and 32) and control seizures (claims 16 and 35) in a patient (paragraph [0064], lines

11–12 and 24). Since incontinence (claim 14) and obesity (claim 15) are intended use claims, Thompson is capable of being adapted to treat incontinence and obesity since Thompson's device uses several different biologically-active compounds to administer several different therapies.

13. Regarding claims 20–22, Thompson discloses one or more sensors operable to deliver a signal to a microcontroller (claim 20) (e.g. Fig. 1, element 70; paragraph [0012]; paragraph [0052], lines 19–22); one or more sensors control release of a drug from a drug delivery module (e.g. paragraph [0056], lines 1–5) and control generation of an electrical current from a neural stimulator to neural tissue (claim 21) (e.g. paragraph [0057], lines 12–15); a drug is an analgesic, an anti-anxiety agent, an anti-incontinence agent, a skeletal muscle relaxant, an anti-convulsant, or an anti-Parkinson agent (claim 22) (e.g. paragraph [0064]).

14. With respect to claims 24–28 and 36, Thompson discloses a drug and an electrical neural stimulation are delivered simultaneously (claim 24) (e.g. paragraph [0037], lines 8 –13); a drug is delivered intermittently or continuously (claim 25) (e.g. paragraph [0011], lines 5–8); an electrical stimulation is delivered intermittently or continuously (claim 26) (e.g. paragraph [0011], lines 5–8); a drug is released before an electrical neural stimulation and is effective to reduce a stimulation threshold of a neural tissue (claim 27) (e.g. paragraphs [0011], lines 5–9 and [0038], lines 4–15); release of a drug is alternated with delivery of an electrical stimulation (claim 28) (e.g. paragraph [0011], lines 5–9); a catheter or tube, a plurality of reservoirs being located proximate to an end of a catheter or tube (e.g. Fig. 6, elements 260 and 262; paragraph [0009], lines 6–8).

Claim Rejections - 35 USC § 102/103

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 17 is rejected under 35 U.S.C. 102(b) as anticipated by Thompson, Patent Application Publication U.S. 2002/0111601 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thompson, in view of Santini, Jr. et al., U.S. Patent 5,797,898.

18. Thompson discloses a drug delivery module comprises a microchip drug delivery device (e.g. Fig. 9, elements 360 and 362).

19. In the alternative for a microchip in claim 17, Thompson does not expressly disclose a drug delivery module comprises a microchip drug delivery device. However, Santini, Jr. discloses a drug delivery module comprises a microchip drug delivery device (e.g. Title of the art) to allow for a device to be small enough to be implantable and to allow the release of a wide

variety of molecules (drugs) in either a continuous or pulsatile manner. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Thompson to include a drug delivery module comprises a microchip drug delivery device, as taught by Thompson to allow for a device to be small enough to be implantable and to allow the release of a wide variety of molecules (drugs) in either a continuous or pulsatile manner.

20. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson as applied to claims 1 and 23 above, and in view of Mann et al., Patent Application Publication U.S. 2002/0055761.

21. Thompson does not disclose a method used to treat incontinence in a patient. However, Mann discloses a medical device for treating incontinence in a patient (e.g. paragraph [0002]) to reduce or eliminate the incidence of unintentional episodes of bladder emptying and to improve the long-term health of the urinary system by increasing bladder capacity and thus, the time period between emptying. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Thompson to include a method used to treat incontinence in a patient, as taught by Mann to improve the health of a patient's urinary system.

22. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson as applied to claim 23 above, and in view of Barrett et al., U.S. Patent 6,587,719.

23. Thompson does not disclose a method used to treat obesity in a patient. However, Barrett discloses a medical device for treating obesity in a patient (e.g. sole Figure; column 8, line 58) to produce a sensation of satiety in the patient to effectively control compulsive overeating. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Thompson to include a method used to treat obesity in a patient, as taught by Barrett to improve a patient's eating habits.

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

25. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
December 5, 2006
5 December 2006

GEORGE R. EVANISKO
PRIMARY EXAMINER
12/7/6